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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/026,610

12/21/2001

Stephen Quirk

15829

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22827

7590

12/15/2006

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EXAMINER

RAMILLANO, LORE JANET

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/026,610

Applicant(s)

QUIRK ET AL.

Examiner

Lore Ramillano

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 113-129 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 113-129 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/4/06 has been entered.
2. In applicant's reply filed on 10/4/06, applicant cancelled claims 95-112; and added new claims 113-129.

Response to Amendment

3. In light of applicant's cancellation of claims 95-112, the rejection over the prior art is withdrawn.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 113-129 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which, was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 113, applicant recites a second

Art Unit: 1743

channel and a second opening. These limitations do not appear to be supported by applicant's specification or drawings because only one channel represented by the numeral (24) and one opening represented by the number (22) are disclosed in applicant's specification and drawings.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 113-129 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 113 is indefinite because the following is not clearly disclosed in applicant's specification and drawings: first opening, first chamber, first channel, second channel, second opening, and second chamber. While the specification and drawings indicate optional chambers (34 and 36), chamber (30), and chamber (56), applicant has not indicated what is considered the first and second chamber. Also, it is unclear whether applicant intends to designate (30) to be a chamber or opening.

For examining purposes, examiner will interpret the invention of claim 113 and applicable claims reciting the second channel and second opening comprising: a first opening (22), a first chamber (30), a first channel (24), and a second chamber (56), a test strip removably attached to the housing at the first chamber (30), and a means for inducing a negative pressure differential on the sample.

Art Unit: 1743

Drawings

8. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the second channel and second opening must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1743

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1743

13. **Claims 113-129** are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Oberhardt ('133), as previously cited.

Oberhardt discloses an analytical device, which comprises all of the presently recited features. Specifically, see Figures 3-4B of Oberhardt depicting an assay device comprising a test element (30) and a means for inducing a pressure differential (syringe) for driving sample fluid to and from the test element. The surface of test element (30) is optically analyzed after contact with the sample (e.g. column 6, lines 20-25).

Regarding the recited limitation that the test surface is a diffraction based surface, including binders printed thereon, see Oberhardt at column 9, first paragraph, teaching that specific binding partners are immobilized on the test surface for interaction with sample analyte. Such immobilization of binding partners is the only definition given by the instant specification for a "diffraction based" surface, and the anticipating structure of Oberhardt therefore implicitly anticipates any presently recited intended use.

Regarding the recited means for inducing a pressure differential as comprising either a positive or negative pressure inducement, see Oberhardt at Figures 4A and 4B disclosing both options.

Regarding the recited means for informing a user that a particular position has been reached, note Figure 3 of Oberhardt. The depicted syringe includes a syringe piston having a diameter greater than the distal end of the syringe chamber. As such,

Art Unit: 1743

the abutment of the syringe piston at the end of its stroke would have provided an indication of its position.

Regarding the recited means for separating and means for diluting, see Oberhardt at column 9, lines 61-65, and column 16, lines 5-8, respectively, teaching these features.

Regarding the recited diffraction enhancing elements, see Oberhardt at column 9, first paragraph, teaching the presence of either magnetic or glass beads. Such beads would have inherently constituted diffraction enhancing elements.

Regarding the recited feature that the test element is removable, see Figure 3 of Oberhardt depicting the test element as connected to the syringe via a luer fitting. Such fitting would have rendered the element removable from the syringe. See also column 6, lines 2-25, disclosing operation of the device as including placing the test element in the testing device, which implies also that the test element can be subsequently removed.

Regarding the recited capillary, see Oberhardt at column 6, lines 45-53 disclosing a capillary providing capillary action as the motive force for transferring sample fluid across the test surface.

Regarding the recited limitations that the housing comprises a second channel and second opening, Oberhardt discloses that his invention may be modified in light of his disclosure and further it has been held that "mere duplication of parts has no patentable significance unless new and unexpected result is produced." *In re Harza*, 124 USPQ 378. Furthermore, it would have been obvious a person of ordinary skill in

Art Unit: 1743

the art to incorporate additional channels and openings to Oberhardt's invention because it would be desirable and more efficient to have a plurality of channels and openings to allow more than one sample to be analyzed simultaneously, or alternatively, it would allow one sample to undergo multiple analyses simultaneously.

Response to Arguments

14. Applicant's arguments filed on 10/4/06 have been fully considered but they are not persuasive.

In response to applicant's argument that Oberhardt lacks certain limitations of the newly presented independent claims (i.e. a second channel), examiner disagrees. Oberhardt discloses that his invention may be modified and varied in light of his disclosure. Furthermore, mere duplication of parts has no patentable significance unless new and unexpected result is produced.

In response to applicant's argument that Oberhardt does not teach the function of having a test strip that is removably attached to a housing, it is noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). In this case, the structure disclosed by Oberhardt would have been fully capable of performing the presently recited operation.

Art Unit: 1743


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lore Ramillano whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lore Ramillano
Examiner
Art Unit 1743

12/3/06


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